

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK**

ONY, INC.,)	Case No. 11-cv-1027-WMS
)	
Plaintiff,)	
v.)	
CORNERSTONE THERAPEUTICS, INC.,))
et al.)	
Defendants.)	
)	

**DEFENDANTS CORNERSTONE THERAPEUTICS, INC., CHIESI FARMACEUTICI,
S.P.A, RANGASAMY RAMANATHAN, JATINDER BHATIA, AND
KRISHNAMURTHY SEKAR'S OPPOSITION TO PLAINTIFF'S CROSS-MOTION
FOR LEAVE TO AMEND THE COMPLAINT**

Defendants Cornerstone Therapeutics, Inc. (“Cornerstone”), Chiesi Farmaceutici S.p.A (“Chiesi”), Rangasamy Ramanathan, Jatinder Bhatia, and Krishnamurthy Sekar (collectively, “Defendants”) respectfully submit this memorandum of law in opposition to the cross-motion of Plaintiff ONY, Inc. (“ONY”) for leave to amend its Complaint (the “Cross-Motion”).

By filing a motion for leave to amend, ONY essentially concedes that its original Complaint failed to state certain claims against Defendants, and ONY does not even attempt to salvage certain of its claims against Cornerstone and Chiesi. In its second attempt to concoct cognizable claims out of a scientific dispute regarding a peer-reviewed article, ONY fails to remedy the deficiencies that warrant dismissal of the claims ONY originally asserted against Defendants, such that the Proposed Amended Complaint would be futile. Accordingly, ONY’s Cross-Motion should be denied.

ARGUMENT

The Court may deny leave to amend where, as here, such amendment would be futile.

See Christian v. Town of Riga, 649 F. Supp. 2d 84, 101 (W.D.N.Y. 2009) (citing *Hom Sui Ching*

v. *United States*, 298 F.3d 174, 180 (2d Cir. 2002)). Amendment would be futile and a motion to amend should be denied “where the amendment would be subject to dismissal for failure to state a claim upon which relief may be granted.” *Christian*, 649 F. Supp. 2d at 101; *see also Milanese & Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 110 (2d Cir. 2001) (stating that leave to amend may be denied as futile “if the proposed new claim cannot withstand a 12(b)(6) motion to dismiss”). The Court should deny ONY’s Cross-Motion because ONY’s Proposed Amended Complaint would be subject to dismissal for failure to state a claim upon which relief may be granted.

I. ONY’s Proposed Amended Complaint Fails to State a Claim for False Advertising Under the Lanham Act.

As Defendants Cornertsone and Chiesi argued in their memorandum in support of their Motion to Dismiss (Dkt. 44) (“Dismissal Brief”) and in their reply brief in support of their Motion to Dismiss (Dkt. 78) (“Reply Brief”), ONY’s original Complaint failed to state a claim for false advertising under the Lanham Act because the conclusions espoused in the article at issue (the “Article”) are properly characterized as opinions, which are not actionable under the Lanham Act, and because ONY failed to plead the claim with particularity. ONY’s Proposed Amended Complaint does not address either of these deficiencies.

While ONY’s Proposed Amended Complaint points to six specific statements in the Article that ONY alleges are false, the substance of ONY’s claim remains that Defendants’ publication, dissemination of, and references to the Article are false and misleading because the ultimate conclusions the Authors drew from the study are based on a faulty data set, do not consider length of stay data, and do not reference allegedly relevant contradictory literature. Proposed Am. Compl. ¶¶ 27, 37, 40, 41, 42, 44, 67. As Defendants explained in their previous briefs, decisions regarding which patients to include in a study and what data and literature are

relevant are methodological decisions that are matters of opinion, not fact. *See* Dismissal Br., at 6-8; Reply Br., at 4.

ONY's Proposed Amended Complaint also fails to plead false advertising with sufficient particularity. As detailed in Defendants' previous briefs, this Court and numerous other courts have held that the pleading requirements of Rule 9(b) apply to false advertising claims that sound in fraud. *See* Dismissal Br., at 9-12; Reply Br., at 6-7. ONY's Proposed Amended Complaint alleges merely that Chiesi and Cornerstone "published the Article, issued press releases repeating the 'findings' of the Article, distributed copies of the same to physicians and hospitals, included the Article on their websites, and otherwise made reference to and repeated" the Article's conclusions. Proposed Am. Compl. ¶ 73. The Proposed Amended Complaint does not comply with the requirements of Rule 9(b) because it fails to identify who distributed the Article, to whom the Article was distributed, and the substance of the other references Defendants allegedly made to the Article.

Because ONY's proposed claim for false advertising under the Lanham Act fails to state a claim upon which relief can be granted, ONY's proposed amendment of this claim would be futile.

II. ONY's Proposed Injurious Falsehood Claims Do Not Adequately Plead a Falsehood, Actual Malice, or Special Damages.

In their memoranda and reply briefs in support of their Motions to Dismiss ONY's original Complaint, Defendants fully addressed how ONY's Complaint failed to plead claims for injurious falsehood because it did not adequately allege a falsehood, actual malice, or special damages. *See* Dismissal Br., at 12-15; Dismissal Brief of Defendants Ramanathan, Bhatia and Sekar (Dkt. 46) ("Authors' Dismissal Brief"), at 12-17; Reply of Defendants Ramanathan, Bhatia and Sekar in Support of Motion to Dismiss (Dkt.77) ("Authors' Reply Brief"), at 7-10.

ONY's proposed injurious falsehood claim differs from the claim ONY asserted in its original Complaint only by the additions of specific statements within the Article that are allegedly false and four specific customers ONY allegedly lost as a result of Defendants' actions. These minor additions are insufficient to salvage ONY's injurious falsehood claims or to adequately allege a falsehood, actual malice, and special damages.

A. ONY's Proposed Claims Fail to Allege a Falsehood.

Like its original Complaint, ONY's proposed injurious falsehood claims are not based upon allegations that the statistical analysis discussed in the Article was performed incorrectly or that Defendants misrepresented the conclusions of the study. Rather, ONY's proposed allegations are based on the choices that Defendants made in determining what data and literature to include and discuss in the underlying study and the Article. Proposed Am. Compl. ¶¶ 27, 37, 40, 41, 42, 44, 67. As Defendants fully explained in their previous briefs, ONY's criticism relates to the study design and the interpretation of the study's results, which are matters of scientific opinion that cannot be the basis of a claim of injurious falsehood. *See* Authors' Reply Br., at 8-10.

B. ONY's Proposed Claims Do Not Allege Actual Malice Adequately.

ONY's Proposed Amended Complaint does not make any changes to its pleading of actual malice. Thus, as Defendants pointed out in their previous briefs, ONY's Proposed Amended Complaint fails to plead actual malice because Defendants' decisions about what data to include and what literature to cite in an academic article are methodological issues that cannot be categorized as true or false; they are simply a matter of academic or scientific opinion. ONY's claim that a different methodology would have been preferable or more reliable does not allege sufficiently that Defendants knew or recklessly disregarded whether the statements were

false. *See* Dismissal Br., at 13-15; Authors' Dismissal Br., at 16-17; Authors' Reply Br., at 10 (citing *Diario El País S.L. v. The Nielsen Co., Inc.*, 2008 U.S. Dist. LEXIS 92987, at *21 (S.D.N.Y. Nov. 6, 2008)).

C. ONY's Proposed Claims Fail to Itemize ONY's Alleged Special Damages.

ONY's addition of the names of four allegedly lost customers is insufficient to satisfy the requirement of itemizing special damages. Special damages must be fully and accurately stated and must include sufficient particularity to identify actual losses. *MapInfo Corp. v. Spatial Re-Engineering Consultants*, 2006 U.S. Dist. LEXIS 70408, at *13 (N.D.N.Y. Sept. 28, 2006). New York law clearly requires that where the alleged special damages are lost customers, "the individuals who ceased to be customers, or who refused to purchase, must be named **and the exact damages itemized.**" *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 59 (2d Cir. 2002) (emphasis added).

In *Alternative Electrodes, LLC v. Empi, Inc.*, the plaintiff's injurious falsehood claim was dismissed despite its inclusion of the names of specific lost customers because plaintiff did not itemize its specific damages. 597 F. Supp. 2d 322, 339-40 (E.D.N.Y. 2009); *see also Proctor & Gamble Company v. Quality King Distributors, Inc.*, 974 F. Supp. 190, 198 (E.D.N.Y. 1997) (dismissing defendant's counterclaim despite inclusion of specific lost customers because defendant merely plead that it suffered damages "in the amount of at least \$ 25 million" and failed to itemize its losses); *Edward B. Beharry & Co. v. Bedessee Imps., Inc.*, 95 U.S.P.Q.2D 1480, 2010 U.S. Dist. LEXIS 27404, at *28-29 (E.D.N.Y. Mar. 23, 2010) (dismissing claim when plaintiff provided only round figures with no attempt at itemization). In contrast, in *General Security, Inc. v. APX Alarm Security Solutions, Inc.*, the court held that plaintiff plead special damages sufficiently because it attempted to itemize the specific damages incurred with

respect to the customers it identified in its complaint by providing estimates of the loss in revenue from each account. 647 F. Supp. 2d 207, 215 (N.D.N.Y. 2009).

Unlike the plaintiff in *General Security*, the Proposed Amended Complaint does not allege any specific figures or estimates of the losses that ONY suffered as a result of Defendants' conduct.¹ ONY's Proposed Amended Complaint is analogous to the complaint that was dismissed in *Alternative Electrodes* because ONY listed customers it allegedly lost due to Defendants' acts but did not itemize its specific damages. Instead of providing a specific dollar figure of the damages it has suffered, as required by New York law, ONY claims that it has been damaged "in an amount to be determined upon the trial of this action." Proposed Am. Compl. ¶¶ 85, 118. Thus, ONY's Proposed Amended Complaint does not plead special damages sufficiently.

Having failed to plead a falsehood, actual malice, and special damages, ONY's proposed injurious falsehood claims would be futile because they fail to state claims upon which relief can be granted.

III. ONY's Proposed Tortious Interference Claims Do Not State Claims Upon Which Relief Can Be Granted.

ONY's Proposed Amended Complaint includes allegations of both tortious interference with existing contracts and tortious interference with prospective contracts. Like the original Complaint, the Proposed Amended Complaint does not make clear with which of the alleged lost customers ONY had contracts and with which alleged lost customers it had only prospective

¹ The only dollar amount that ONY provides in its Proposed Amended Complaint is an alleged diminution of ten percent in the inherent value of ONY's business. Proposed Am. Compl. ¶¶ 84, 117. However, the Proposed Amended Complaint makes clear that any loss in inherent value is itself due to lost sales. *Id.* ONY cannot evade the requirement of itemizing damages by categorizing its damages as a diminution in the inherent value of its business when the substance of its claims is that it has lost customers.

business relationships. Under either the theory of tortious interference with a contract or with a prospective economic advantage, ONY's Proposed Amended Complaint fails to state a claim upon which relief can be granted.

A. ONY's Proposed Claim for Tortious Interference with a Contract Fails to State a Claim Upon Which Relief Can Be Granted.

ONY's Proposed Amended Complaint fails to state a claim for tortious interference with a contract. In New York, the tort of interference with contractual relations consists of five elements: (1) the existence of a valid contract between plaintiff and a third party; (2) defendant's knowledge of the contract; (3) defendant's intentional inducement of the third-party's breach of contract without justification; (4) actual breach of the contract; and (5) defendant's interferences caused damages to plaintiff. *Lama Holdings Co. v. Smith Barney Inc.*, 646 N.Y.S.2d 76 (1996). ONY's Proposed Amended Complaint fails to allege sufficiently the existence of a valid contract, Defendants' knowledge of that contract, breach of the contract, or causation of damages.

To state a claim for tortious interference with a contract, it is insufficient to state that there was a contractual relationship; the plaintiff must refer to a valid, existing contract with a third party. *See G-I Holdings, Inc. v. Baron & Budd*, 179 F. Supp. 2d 233, 253 (S.D.N.Y. 2001) (dismissing claim where plaintiff plead a "contractual relationship" with a third party and described the nature of the relationship and specific benefits derived from it but failed to identify a valid, existing contract); *Martin Ice Cream Co. v. Chipwich, Inc.*, 554 F. Supp. 933, 945 (S.D.N.Y. 1983) (allegation of interference with "contractual relations" found insufficient). ONY's Proposed Amended Complaint fails to identify any valid, existing contracts with third parties and instead merely pleads that Defendants' actions interfered with existing contracts Plaintiff had with "various hospitals and physicians." Proposed Am. Compl. ¶ 123.

A correctly plead complaint must also allege that Defendants knew of the contracts between ONY and the third parties and intentionally interfered with them. *See Am. Bldg. Maint. Co. v. ACME Prop. Servs.*, 515 F. Supp. 2d 298, 323 (N.D.N.Y 2007) (dismissing tortious interference claim as conclusory where plaintiff failed to allege that defendant knew of the specific contracts and business relationships at issue). This element requires direct interference with a third party, that is, “the defendant must direct some activities towards the third party and convince the third party not to enter into a business relationship with the plaintiff.” *Fonar Corp. v. Magnetic Resonance Plus, Inc.*, 957 F. Supp. 477, 482 (S.D.N.Y. 1997); *see also Black Radio Network, Inc. v. NYNEX Corp.*, 2000 U.S. Dist. LEXIS 594, at *14 (S.D.N.Y. Jan. 25, 2000) (dismissing claim for failure to allege that defendant directed any conduct towards plaintiff’s customers or prospective customers). Although ONY amended its tortious interference claim to specify relationships with four hospitals with which Defendants allegedly interfered, its Proposed Amended Complaint fails to allege that Defendants knew of and intentionally interfered with any specific contracts. The proposed claim alleges merely that Defendants “were aware of hospitals and physicians who purchased and utilized Infasurf®.” Proposed Am. Compl. ¶ 120. There is no allegation that Defendants disseminated the Article to any specific hospitals or physicians, much less to hospitals or physicians that Defendants knew had existing contracts with ONY.

Moreover, New York law requires that to plead tortious interference with a contract properly, the plaintiff must allege that an existing contract was breached. *See G-I Holdings*, 179 F. Supp. 2d at 253 (dismissing claim where plaintiff failed to plead that existing contract was breached); *Robins v. Max Mara, U.S.A., Inc.*, 923 F. Supp. 460, 468 (S.D.N.Y. 1996). ONY’s Proposed Amended Complaint alleges only that Defendants “did in fact interfere with” ONY’s

existing contracts and fails to allege that any existing contract was breached. Proposed Am. Compl. ¶ 123.

The U.S. Supreme Court has made clear that a complaint must contain sufficient factual matter to state a claim that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009). Conclusory allegations that merely state the general legal conclusions necessary to prevail on the merits but are unsupported by factual averments should not be accepted as true. *New York State Teamsters Council Health and Hosp. Fund v. Centrus Pharmacy Solutions*, 235 F. Supp. 2d 123, 126 (N.D.N.Y. 2002). Thus, to plead its tortious interference claim correctly, ONY must allege some factual basis for its claim that there would not have been a breach of the existing contracts “but for” Defendants’ actions.

ONY’s Proposed Amended Complaint provides no factual basis for its assertion that Defendant’s publication and/or dissemination of the Article was the proximate cause of breached contract or any lost sales to the four specified hospitals. The Proposed Amended Complaint does not allege that Defendants disseminated the Article to these hospitals or that any individuals associated with the hospitals ever read the Article. ONY’s bald allegation that Defendants’ actions were the proximate cause of these hospitals’ decisions is not plausible and cannot salvage ONY’s tortious interference claim.

Having failed to allege the existence of a valid contract, Defendants’ knowledge of that contract, breach of the contract, or causation of damages, ONY’s Proposed Amended Complaint does not state a claim for tortious interference with a contract.

B. ONY Proposed Amended Complaint Fails to Adequately Plead a Claim for Tortious Interference with Prospective Economic Advantage.

ONY’s proposed claim for tortious interference with prospective economic advantage also fails to state a claim upon which relief can be granted. To state a claim for tortious

interference with prospective economic advantage in New York, the plaintiff must allege that “(1) it had a business relationship with a third party; (2) the defendant knew of that relationship and intentionally interfered with it; (3) the defendant acted solely out of malice, or used dishonest, unfair, or improper means; and (4) the defendant's interference caused injury to the relationship.” *Kirch v. Liberty Media Corp.*, 449 F.3d 388, 400 (2d Cir. 2006).² As discussed above, ONY’s Proposed Amended Complaint does not allege either that Defendants knew of any specific business relationships ONY had with the four hospitals ONY identified as lost customers or that Defendants intentionally interfered with those relationships. ONY’s Proposed Amended Complaint also fails to provide an adequate factual basis for its allegation that Defendants’ actions were the proximate cause of any of the decisions of any of these hospitals not to purchase Infasurf.

Additionally, ONY’s proposed claim for tortious interference with prospective economic advantage is not plead with sufficient particularity. One element of such a claim is that defendant acted solely out of malice or used dishonest, unfair, or improper means. The phrase “dishonest, unfair, or improper means” is generally defined as misconduct that constitutes either a crime or an independent tort. *See Carvel Corp. v. Noonan*, 785 N.Y.S.2d 359 (2004). Here, ONY’s Proposed Amended Complaint alleges that Defendants “knowingly and intentionally manipulated, fabricated and disseminated an Article containing information known by them to be

² Allegations of tortious interference must be more than just mere suspicions, and, therefore, a complaint must allege interference with specifically identified business relationships. *Camp Summit of Summitville, Inc. v. Visinski*, 2007 U.S. Dist. LEXIS 28496, at *43 (S.D.N.Y. Apr. 16, 2007). Thus, any claim ONY may have alleged would be limited to the four specific relationships identified in the Proposed Amended Complaint as relationships with which Defendants interfered. ONY may not plead that Defendants interfered with “existing and prospective contracts which Plaintiff had or would have had with various hospitals and physicians” in general and expect to be able to allege additional lost accounts at a later date. *See* Proposed Am. Compl. ¶ 123.

false and misleading,” Proposed Am. Compl. ¶ 121, and that “[t]hese deceptive and unethical practices constitute wrongful means,” *id.* at ¶ 122. ONY’s claim therefore hinges on the independent tort of fraud.

Allegations of fraud must be plead with particularity. Fed. R. Civ. Pro. 9(b). Particularity requires that the Complaint: (1) specify the allegedly fraudulent statements; (2) identify the speaker; (3) state where and when the statements were made; and (4) explain why the statements were fraudulent. *Anatian v. Coutts Bank Ltd.*, 193 F.3d 85, 88 (2d Cir. 1999). ONY’s proposed tortious interference claim alleges only that Defendants knowingly and intentionally disseminated information they knew was false and misleading, but does not identify either who disseminated the Article or to whom, where, and when the Article was disseminated. *See* Proposed Am. Compl. ¶ 121. Thus, ONY’s proposed claim for tortious interference with prospective economic advantage does not state a claim for which relief can be granted. *See Thacker v. Medaphis Corp.*, 1998 U.S. Dist. LEXIS 15270, at *14-15 (S.D.N.Y. Sept. 30, 1998) (dismissing plaintiffs’ claim for tortious interference when it incorporated by reference fraud claims that had not be plead with sufficient particularity).

IV. ONY’s Proposed Amended Complaint Fails to Allege a Claim Under General Business Law § 349.

Defendants Cornerstone and Chiesi explained in their Dismissal Brief and Reply Brief that ONY’s original claim under General Business Law § 349 was deficient because it failed to allege injury to consumers. *See* Dismissal Br., at 19-21; Reply Br., at 8-9. ONY’s Proposed Amended Complaint does not amend any of the allegations related to its claim under General Business Law § 349. Thus, the Proposed Amended Complaint continues to fail to state a claim under General Business Law § 349 upon which relief can be granted.

CONCLUSION

For the foregoing reasons, Defendants respectfully submit that ONY's Cross-Motion should be denied as futile because ONY's Proposed Amended Complaint fails to plead any claim against Defendants upon which relief can be granted.

DATED: February 24, 2012

Respectfully submitted,

/s/ J. Kevin Fee

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on February 24, 2012, I electronically filed the foregoing Opposition to Plaintiff's Cross-Motion to Amend with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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